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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/594,065	06/14/2000	Cindy WalkerPeach	25436/1280	7768

27495 7590 06/30/2003

PALMER & DODGE, LLP  
KATHLEEN M. WILLIAMS / STR  
111 HUNTINGTON AVENUE  
BOSTON, MA 02199

EXAMINER

FOLEY, SHANON A

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/594,065

Applicant(s)

WALKERPEACH ET AL.

Examiner

Shanon Foley

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 June 2000.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

### DETAILED ACTION

It cannot be determined if there is a difference between the polynucleotides designated by SEQ ID NO: 3 listed in the alternative in claims 6, 20, 29 and 32. In the interest of compact prosecution, each SEQ ID NO: "3" is interpreted as containing a different polynucleotide sequence to justify the existence of the alternative language present in the claims. Applicant is requested to clarify this issue in the response to the restriction requirement.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- 1-11. Claim 1, drawn to a purified polynucleotide, classified in class 536, subclass 23.1.

Each of inventions 1-11 correspond to each purified polynucleotide listed in consecutive order, i.e, SEQ ID NO: 1-11.

12. Claim 2, drawn to a pair of primers SEQ ID NO: 1 and SEQ ID NO: 2, classified in class 536, subclass 24.33.

13. Claims 3-22, drawn to a polynucleotide for HSV detection comprising SEQ ID NO: 4 and kits comprising SEQ ID NO: 4, classified in class 536, subclass 23.72.

14. Claims 23-34, drawn to a method of HSV detection, classified in class 435, subclasses 5 and 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-11 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are structurally and functionally distinct, as evidenced by a separately designated SEQ

Art Unit: 1648

ID NO. Each of the polynucleotide sequences would express a different product and would have different binding affinities to other nucleic acids. Therefore, inventions 1-11 have different functions and produce different effects.

Inventions 1-11 and 12 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the primer pair of claim 2 is specifically used to amplify a nucleic acid sequence and must be used together. The nucleic acid sequences of groups 1-11 are individually distinct and can be used individually as probes. Therefore, the inventions 1-11 and 12 have different modes of operation and have different functions and different effects.

Inventions 1-3, 5-12 and 13 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, group 13 is drawn to a specific SEQ ID NO:4 and kits comprising this sequence used to detect HSV. The single nucleic acids of groups 1-3 and 5-11 express different products and can be used individually to hybridize to different nucleic acids and the primer pairs of group 12 are used to amplify a specific sequence. SEQ ID NO: 4 cannot amplify a sequence and cannot hybridize to the same polynucleotide structures SEQ ID NOs: 1-3 and 5-12 hybridize to. Therefore, each of the nucleic acids have different functions and different effects.

Inventions 1-13 and 14 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

Art Unit: 1648

as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of detecting the presence of HSV can be practiced with materially different products, such as detecting HSV with an antibody.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Application/Control Number: 09/594,065

Page 5

Art Unit: 1648

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Sharon Foley  
June 28, 2003